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Section 2, HFASB (H7509C)

DATA EVALUATION REPORT IV

STUDY TYPE: Primary eye irritation in rabbits TOX CHEM NO. 309BB

MRID NO: ACC. NO: 408064-5

TEST MATERIAL: TD 2073 (97.0%)

SYNONYMS: Potassium 3,4-dichloro-5-isothiazole carboxylate
AC 303,358 Chemical Hybridizing Agent; CHEMBRED

STUDY NUMBER(S): WIL-75019

SPONSOR: Pennwalt Corporation
Agrichemical Division
P.O. Box 1027
Puyallup, Washington 98371

TESTING FACILITY: Wil Research Laboratories, Inc.
Ashland, Ohio 44805-9281

TITLE OF REPORT: Primary Eye Irritation Study in Albino Rabbits with TD 2073

AUTHOR(S): Naas, D. J.

REPORT ISSUED: 1/9/86

CLASSIFICATION: Core minimum data (Toxicity Category I)

CONCLUSIONS:

1. Although observations were not made after day 7, the severity of the corneal opacity in the unwashed eyes, along with a lack of improvement in this condition in the period from day 1 through day 7, indicate the test material is in toxicity category I in terms of its eye irritation potential.

A. MATERIALS:

1. Test compound: TD 2073, 97.0%, lot no. N.B. 86-58-1. Described as on off-white powder.

2. Animals used: New Zealand white rabbits from Mohican Valley Rabbitry, Loudonville, Ohio. The rabbits

weighed from 2308 to 3055 grams at the start of the study.

B. STUDY DESIGN:

1. Test material administration: One hundred milligrams of the test material were instilled into the lower conjunctival sac of the right eye of each of 9 rabbits. Six eyes were unwashed, while 3 were washed with 120 mls of tap water for one minute starting 30 seconds after test material administration.

2. Quality assurance: There is a signed and dated Good Laboratory Practices Compliance Statement on p. 3 of the report, which states: "The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160." There is a laboratory Quality Assurance Unit Statement on p. 15.

C. METHODS AND RESULTS:

1. Observations: "Both eyes of all rabbits were examined for ocular irritation at approximately one, 24, 48, 72 and 96 hours and 7 days after dosing. In addition, both eyes of all rabbits were further examined at 72 hours and 7 days with sodium fluorescein stain and ultraviolet light."

Results:

All unwashed eyes showed extensive corneal opacity (4/6 rabbits had maximum scores for corneal involvement in the period from 1 hour through day 7). On day 7 (last day of readings) the mean Draize irritation for the unwashed eyes was 89.67.

Some corneal involvement was present in all 3 washed eyes, although 2/3 had essentially cleared (no irritation present) by day 7. 1/3 washed eyes still showed corneal opacity (although not as extensive as that observed in the washed eyes) on day 7.

D. DISCUSSION:

Although observations were not made after day 7, the extensive corneal opacity along with what was essentially a lack of improvement in this condition in the period from day 1 through 7, indicate the test material is in toxicity category I in terms of eye irritation hazard potential.

The study is classified as core minimum data.